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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/271,098	03/18/99	CHERN	R 20023Y

000210
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EXAMINER	
SHARAREH, S	
ART UNIT	**PAPER NUMBER**
1616	6

DATE MAILED: 11/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/271,098	Chern et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

☒ Responsive to communication(s) filed on *Mar 18, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-14* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4, 5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed July 12, 1999 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, the following foreign patent: EP 0 179 022, EP 0 508 699, EP 0 846 686, EP 0 295 117, EP 0 892 060, EP 0 007 812, EP 0 002 916, and WO 96/29073.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 5-6, 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant claims, it is not clear whether the percentages for the indvidual claimed inventions are based on the weight or volume of the instant inventions.

5. Please modify the claim language in claims 2-11, dependents of claim 1, to read "the composition" instead of "a composition."

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 8-11, 13 rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al US Patent 5,278,202.

The instant claims are directed to liquid polymeric compositions comprising a hydrophobic bioactive substance, a poly(lactide-co-glycolide) copolymer, and a mixture of hydrophilic with lipophilic solvents.

Dunn et al disclose liquid polymeric compositions comprising hydrophobic bioactive substances such as sedatives, tranquilizers , progestational agent (see col 6 lines 58-68, col 7 lines 1-15.), various biocompatible polymers such as poly(lactide-co-glycolide) copolymer (see col 4 lines 47-68, col 7 lines 61-68, example 6), and a mixture of hydrophilic and lipophilic solvents (see col 5 lines 4-22, and lines 55-67.) Therefore, Dunn et al meet the limitations set forth in the instant claims.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 1-14 rejected under 35 U.S.C. 102(e) as being anticipated by Yewey et al US Patent 5,780,044.

The instant claims are directed to liquid polymeric compositions comprising a hydrophobic bioactive substance, a poly(lactide-co-glycolide) copolymer, and a mixture of hydrophilic with lipophilic solvents; as well as methods of using said composition.

Dunn et al disclose liquid polymeric compositions comprising hydrophobic bioactive substances such as sedatives, tranquilizers , progestational agent (see col 6 lines 58-68, col 7 lines 1-15.), various biocompatible polymers such as poly(lactide-co-glycolide) copolymer (see col 4 lines 47-68, col 7 lines 61-68, example 6), and a mixture of hydrophilic and lipophilic solvents (see col 5 lines 4-22, and lines 55-67.)

Yewey et al disclose liquid polymeric compositions comprising a hydrophobic bioactive substance such as various hormones or growth factors (see col 14 lines 20-30), various biocompatible polymers and copolymers such as poly(lactide-co-glycolide) (see col 8, lines 24-42.), and a mixture of hydrophilic such as 2-pyrrolidone (see col 11 lines 50-68) and lipophilic solvents (see col 12 lines 4-9) in varying degrees of solubility for the polymer components allowing varying coagulation rate of the polymers (see col 12, lines 16-38. example 1, 6 and 7). Yewey also disclose methods of controlled drug delivery utilizing their compositions. Therefore, Yewey et al meet the limitations set forth in the instant claims.

9. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis US Patent 5,733,566.

The instant claims are directed to liquid polymeric compositions comprising a hydrophobic bioactive substance, a poly(lactide-co-glycolide) copolymer, and a mixture of hydrophilic with lipophilic solvents; as well as methods of using said composition.

Lewis disclose liquid polymeric compositions comprising a hydrophobic bioactive substance such as Avermectins or growth promoters (see col 13 lines 20-41, col 15 lines 12-38), various biocompatible polymers and copolymers such as poly(lactide-co-glycolide) (see col 5 lines 15-20, example 1, claim 10), and a mixture of aqueous and non-aqueous solvents known in the art (see col 11 lines 55-68, col 12) in various drug:polymer ratios that provides controlled duration of action preferable between 30-270 days (see col 12 lines 50-59, and col 13 lines 1-19.) Therefore, Lewis meet the limitations set forth in the instant claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al US Patent 5,278,202, Yewey et al US Patent 5,780,044 and Lewis et al US Patent 5,733,566.

The instant claims are directed to liquid polymeric compositions comprising a hydrophobic bioactive substance, a poly(lactide-co-glycolide) copolymer, and a mixture of hydrophilic with lipophilic solvents; as well as methods of using said composition.

Yewey et al disclose liquid polymeric compositions comprising a hydrophobic bioactive substance such as various hormones or growth factors (see col 14 lines 20-30), various biocompatible polymers and copolymers such as poly(lactide-co-glycolide) (see col 8, lines 24-42.), and a mixture of hydrophilic such as 2-pyrrolidone (see col 11 lines 50-68) and lipophilic solvents (see col 12 lines 4-9) in varying degrees of solubility for the polymer components allowing varying coagulation rate of the polymers (see col 12, lines 16-38. example 1, 6 and 7). Yewey also disclose methods of controlled drug delivery utilizing their compositions.

Lewis disclose liquid polymeric compositions comprising a hydrophobic bioactive substance such as Avermectins or growth promoters (see col 13 lines 20-41, col 15 lines 12-38), various biocompatible polymers and copolymers such as poly(lactide-co-glycolide) (see col 5 lines 15-20, example 1, claim 10), and a mixture of aqueous and non-aqueous solvents known in the art (see col 11 lines 55-68, col 12) in various drug:polymer ratios that provides controlled duration of action preferable between 30-270 days (see col 12 lines 50-59, and col 13 lines 1-19.)

Dunn, Yewey and Lewis all disclose methods of making and using biocompatible liquid polymeric compositions as sustained release drug delivery systems, therefore, they are viewed as being in the same field of endeavor.

An Official Notice is taken that it is well within the skill of the art to control the rate of precipitation of liquid polymeric compositions by changing the overall hydrophobicity/hydrophilicity of the copolymers. For example, using higher ratios of hydrophobic copolymers in a polymeric composition makes such compositions to precipitate in a faster rate.

Although Dunn et al does not disclose various ratios of copolymers and or suitable bioactive agents such as Avermectins in their teachings, one skilled in the art would have been motivated to improve the duration of action by modifying the ratios of the polymeric ingredients as thought by Yewey or Lewis to enhance the efficacy of the compositions of Dunn et al. Further, although Dunn did not fully disclose various types of bioactive agents in their teachings; it would have been obvious to one ordinary skilled in the art at the time of invention to incorporate various bioactive substances such as progesterone derivatives or Avermectins as taught by Yewey and Lewis to make a polymeric composition that is specific to treat a special medical condition such as parasitic infections. Subsequently, the use of said polymeric composition as a controlled release therapeutic delivery system would have also been obvious.

Conclusion

No claims were allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose

telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs, 10/26/99

S. MARK CLARDY
PATENT EXAMINER
GROUP ~~1200~~ 1616

Acting SPE